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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,158	08/01/2001	Yong Hua Zhu	LOMAU.138A	7213
20995	7590	06/14/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			ROBERTS, PAUL A	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			3731	

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/921,158

Applicant(s)

ZHU, YONG HUA

Examiner

Paul A Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-26 and 46-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-15, 17-26 and 46-52 is/are allowed.
- 6) ☒ Claim(s) 53, 55-58, 60-71 is/are rejected.
- 7) ☒ Claim(s) 54 and 59 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/1/2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date dec 12 2003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 58, 62, and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Akerfeldt et al. 6,508,828. Akerfeldt et al. discloses a method of sealing a wound comprising locating the wound, positioning a surgical implement so that a portion of the implement (4, figure 12) extends through the wound and a portion extends out of the wound, and that the surgical implement substantially plugs the wound (shown in figure 13), providing a push member 22 which slides over the implement, providing a hemostatic material 6, positioning the material on the outer surface of the implement, engaging the material with the push member over the implement, so that the material engages the wall of the vessel adjacent the wound. The material is threaded by the suture 4. The process of threading the material is within the scope of poking the thread through the material.

2. Claim 60 is rejected under 35 U.S.C. 102(e) as being anticipated by Prosl et al. 2003/0167050. Prosl et al. discloses a method comprising locating a wound, positioning a surgical implement so that a portion extends out of the wound, so that the surgical implement plugs the wound, providing a hemostatic material (12), advancing the material over the

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implement (this step occurs when the sponge is set up on the implement), adhesive is placed on the hemostatic material.

3. Claims 62, 63, 64, 65, and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Janzen 5437631. Janzen discloses a method of closing a blood vessel wound. The method comprises locating the wound, making a passage to the wound, positioning a surgical implement so that a portion of the implement extends through the wound and a portion extends out of the wound, and so that the surgical implement substantially plugs the wound (14), providing a hemostatic material (48), positioning the material on the outer surface of the implement (figure 5), advancing the material distally, over the implement so that the hemostatic material engages an outer wall of the blood vessel adjacent the wound.

Regarding claim 63, the push member is element 45.

Regarding claim 64, the anti-microbial fluid is the 2nd hemostatic material. The implement will be removed from the wound once the sponge is seated in the puncture.

Regarding claim 65, flowable adhesive is inserted into the sponge.

Regarding claim 69, the sponge is highly elastic, the adhesive on the second side of the hemostatic object act as a hemostatic agent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 53, 55, 56, 57, 66, and 67, are rejected under 35 U.S.C. 103(a) as being unpatentable over Janzen US 5437631 in view of Zhu et al 2001/0053922. Janzen discloses a method of closing a blood vessel wound. The method comprises locating the wound, making a passage to the wound, positioning a surgical implement so that a portion of the implement extends through the wound and a portion extends out of the wound, and so that the surgical implement substantially plugs the wound (14), providing a hemostatic material (48), positioning the material on the outer surface of the implement (figure 5), advancing the material distally, over the implement so that the hemostatic material engages an outer wall of the blood vessel adjacent the wound. Janzen does not disclose using suction in combination with this method. Zhu et al. teaches using suction, "Due to the use of a vacuum, contaminants and blood clots are cleaned off the puncture site allowing better healing of the wound. Also, re-entry is made easier and less scarring is produced." At the time of the invention it would have been obvious to one having ordinary skill in the art to use a vacuum as taught by Zhu et al. with the Janzen hemostatic method because, "Due to the use of a vacuum, contaminants and blood clots are cleaned off the puncture site allowing better healing of the wound. Also, re-entry is made easier and less scarring is produced."

Regarding claim 55, an elongate catheter composes the surgical implement.

Regarding claim 56, the push member is element 45.

Regarding claim 57, the push member comprises a lumen that surrounds the implement.

5. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prosl et al '050 in view of Zhu et al '922. Prosl et al. discloses all of claim 60. Prosl et al. does not disclose using suction in combination with this method. Zhu et al. teaches using suction, "Due to the use of a

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vacuum, contaminants and blood clots are cleaned off the puncture site allowing better healing of the wound. Also, re-entry is made easier and less scarring is produced.” At the time of the invention it would have been obvious to one having ordinary skill in the art to use a vacuum as taught by Zhu et al. with the Prosl hemostatic method because, “Due to the use of a vacuum, contaminants and blood clots are cleaned off the puncture site allowing better healing of the wound. Also, re-entry is made easier and less scarring is produced.”

6. Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prosl ‘050. Prosl discloses using an ‘appropriate’ adhesive with the method of claim 62. One of the most common adhesives used vessel repair is fibrin glue. This adhesive forms a strong bond with the skin, is bioabsorbable, and is a blood clotting agent. At the time of the invention it would have been obvious to one having ordinary skill in the art to use fibrin glue with the Prosl ‘050 method because fibrin glue is commonly used for blood clotting by those of ordinary skill in the art since the material is bioabsorbable and forms an effective seal with blood vessels.

7. Claims 70 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akerfeldt ‘828 in view of Myers et al. 5486195. Akerfeldt discloses claim 62, but does not disclose using a medical adhesive with his device. Myers et al. discloses a device of similar structure (two surface that meet together to seal a wound in a blood vessel). Myers et al. uses fibrin glue to seal the two surfaces together. Using glue inherently helps create a more permanent repair of the blood vessel. At the time of the invention it would have been obvious to one having ordinary skill in the art to use fibrin glue as taught by Myers et al. in the Akerfeldt device because fibrin glue can seal the plates together as demonstrated in the Myers et al. patent.

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Regarding claim 71, the surgical implement (4) effectively prevents the material from entering the wound.

Allowable Subject Matter

Claims 1-15, 17-26, and 46-52 are allowed. Claims 54 and 59 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 1-9, and 46-49, these claims were previously indicated to contain allowable subject matter.

Regarding claims 10-15, 17-26, and 50-52, the amendments of claim 10 on April 22, 2004 are sufficient to overcome the prior rejections and cited prior art.

Regarding claim 54, the cited prior art does not disclose a device having retractor arms.

Regarding claim 59, the cited prior art does not contain a multi-layer hemostatic material.

Conclusion

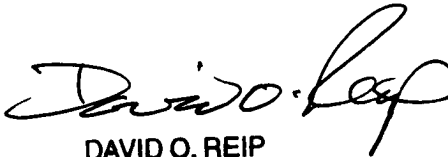
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on 703-308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Roberts
Paul.Roberts@uspto.gov
06/08/04



DAVID O. REIP
PRIMARY EXAMINER